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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:)
Stephen C. Wardlaw, et al.) Examiner: A. Bhat
) Group Art Unit: 2863
Title: APPARATUS FOR PROVIDING)
QUALITY CONTROL IN AN)
INSTRUMENT FOR MEDICAL)
ANALYSIS)
Serial No.: Unknown) (Our Docket No. 5169-0011-1-1)
Filed: Herewith)

Hartford, Connecticut, December 11, 2003

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

S I R:

Applicant(s) submits herewith Form PTO/SB/08A identifying patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 CFR 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this Information Disclosure Statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Under 37 CFR 1.97 (b)

☒ This Information Disclosure Statement is being filed within three months of the filing date of the application, or the date of entry into the national stage of an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

Under 37 CFR 1.97 (c)

☐ This Information Disclosure Statement is being filed *after* three months of the filing date of this national application, or the date of entry into the national stage as set forth in §1.491 in an international application, or after the mailing date of the first Office Action on the merits, whichever event occurred last, but *before* the mailing date of either a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first.

☐ A certification as specified in 37 CFR 1.97(e) is set forth below or

☐ Fee as set forth in 37 CFR 1.17(p) (\$180.00).

Under 37 CFR 1.97(d)

☐ This Information Disclosure Statement is being filed *after* a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee. Applicant hereby petitions for the consideration of this Information Disclosure Statement, 37 CFR 1.97(d)(ii). A certification as specified in 37 CFR 1.97(e) is set forth below.

☐ A certification as specified in 37 CFR 1.97(e) is set forth below and

☐ Fee as set forth in 37 CFR 1.17(p) (\$180.00).

CERTIFICATION (37 CFR 1.97(e))

☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. A copy of the relevant search report is enclosed herewith.

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing this certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Statement.

Under 37 CFR 1.98(a)(2)(i)

☒ Because the above-referenced application was filed after June 30, 2003, pursuant to USPTO Notice dated 7/11/2003 ("*Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications filed after June 30, 2003*") Applicant(s) do not provide copies of the U.S. patents identified on the attached PTO/SB/08A form at this time. Should the Examiner require the U.S. patent copies, Applicants respectfully request the Examiner contact Applicants' Representative at the number listed below.

Applicants respectfully request that any deficiencies in the fees be charged to Deposit Order Account No. 13-0235.

Respectfully submitted,

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By Richard D. Getz
Richard D. Getz
Registration No. 36,147
Attorney for Applicant

Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (08-00)
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	New		
		Filing Date	Herewith		
		First Named Inventor	STEPHEN C. WARDLAW. et al		
		Group Art Unit	2863		
		Examiner Name	A. Bhat		
Sheet	2	of	2	Attorney Docket Number	5169-0011-1-1

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Information on CLIA Waivers (Clinical Laboratory Improvement Amendments) pages 1-2	
		CLIA Categorization Criteria, pages 1-2	
		CLIA Home Page - Clinical Laboratory Improvement Amendments, pages 1-2	
		Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA Applications pages 1-22	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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